REMARKS

Claims 1-11 were pending in this application. According to the May 8, 2002 Office Action, claims 1-11 were rejected.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-11 under 35 U.S.C. §103(a) as allegedly being unpatentable over Fuisz in view of Yamamoto et al., Bodmer et al. and Canal et al.

In response, Applicants respectfully traverse the Examiner's rejection. Fuisz describes the preparation of controlled release delivery systems by melt-spun process. This process is characterized in that the product obtained is a uniform mixture of encapsulating agent (polymer) and drug. Therefore, a drug is present on the surface of the particles obtained by this method. The product according to the present patent application is obtained by a process that yields a product constituted by a **nucleus** of drug, which is coated by a layer of polymer. Therefore, the release of the drug from the microcapsules according to the present patent application are completely different from the product described in Fuisz. On the other hand, to prepare delivery systems following the process described in Fuisz, it is necessary to use some processing helpers that remain inside the final product (in Fuisz, they use MCT (medium chain triglycerides) as default helper or sucrose when they do not use MCT, see examples). For this reason, the product described in Fuisz is not a combination of polymer + drug + citric acid esters (as the product according to the present application is). The product described in Fuisz always contains a process helper. Accordingly, it is not possible to obtain the microcapsules according to the present application by the process disclosed in Fuisz.

Yamamoto et al., Bodmer et al. and Canal et al. all describe the preparation of microcapsules incorporating different drugs, using copolymers of lactic glycolic, but none of the said references teaches the use of citric acid esters or suggests the use of citric acid esters in order to improve the properties of the microcapsules. The incorporation of citric acid esters to the product according to the present application is essential for the regulation of the release of the drug from the microcapsules, and different drug release profiles can be achieved just by changing the content of citric acid esters in the microcapsules.

Accordingly, Applicants respectfully submit that the references cited either alone or in combination do not disclose nor suggest the present invention. Thus, the Examiner is kindly requested to withdraw this rejection.

In light of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 1, 2002:

Charles C. Achkar
Name of applicant, assignee or Registered Representative

Signature

August 1, 2002
Date of Signature

WOG/CCA:lac

Respectfully submitted,

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